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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,395

06/23/2003

Charles L. Guy

UF-326XC1

1698

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10/31/2006

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER

KUMAR, VINOD

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,395

Applicant(s)

GUY ET AL.

Examiner

Vinod Kumar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13,15-23,25-32,34-39 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-13,15-23,25-32,34-39 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claims 20-30 and 33-39 under 101, is withdrawn in light of claim amendments.
3. The rejection of claims 1-5, 8-24 and 27-39 under 112, second paragraph, is withdrawn in light of claim amendments.
4. The rejections of claims 1-5, 8-24 and 27-39 under 112, first paragraph, are withdrawn in light of claim amendments.
5. The rejection of claims 1, 5, 9-10, 14-20, 24, 28-29 and 33-39 under 102(b) is withdrawn in light of claim amendments.

Claim Rejections-35 USC § 112

6. Claims 6-7 and 25-26 remain and newly added claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons of record stated in Office action mailed March 13, 2006. Applicants traverse the rejection in the paper filed August 17, 2006.

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Applicants argue that the recitation "reduced inhibition by maltose" in claims 6 and 25 contemplates an enzyme whose enzymatic activity is less inhibited by maltose than normal plant β -amylase enzyme (response, page 9, lines 1-6)

Applicant's argument was fully considered but was not found persuasive. It is unclear how instantly claimed β -amylase enzyme is different from a normal β -amylase enzyme. Do they differ in amino acid sequence? Furthermore, examiner maintains that metes and bounds of the recitation "reduced" are not defined. Accordingly, the rejection is maintained.

Applicants argue that β -amylase enzyme that exhibit "increased thermostability" as recited in claims 7 and 26 is well known in the art, and one skilled in the art would understand metes and bounds of the claims (response, page 9, lines 7-13).

Applicant's argument was fully considered but was not found persuasive. Examiner maintains that the recitation "increased thermostability" is indefinite because one skilled in the art would not know the comparative basis of the recitation because metes and bounds are undefined. Accordingly, the rejection is maintained.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "breeding a plant", which is confusing, since it is unclear how a plant cell or tissue is bred. It is unclear what is intended. It is also unclear whether the plant, tissue or cell comprises the polynucleotide. Accordingly, the claim is rejected.

Claim Rejections - 35 USC § 112

7. Claims 6-7 and 25-26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a stress resistant transgenic plant or

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a method for producing said transgenic plant comprising expression of a polynucleotide sequence encoding β -amylase, does not provide enablement for a transgenic plant or a method of producing said plant with increased resistance to stress comprising expression of a polynucleotide sequence encoding a β -amylase enzyme which exhibits reduced inhibition by maltose or increased thermostability. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons of record stated in Office action mailed on March 13, 2006. Applicants traverse the rejection in the paper filed August 17, 2006. Applicant's arguments were fully considered but were not found persuasive.

Applicants argue that amylase enzymes that are thermostable or that exhibit reduced inhibition by maltose are known in the art to an ordinarily skilled artisan (response, page 10, lines 12-15).

Applicant's arguments were fully considered but were not found persuasive. Examiner maintains that specification does not provide guidance on how a wild type amino acid sequence of any β -amylase could be altered so that the modified or mutant form of β -amylase becomes thermostable and/or exhibits reduced inhibition by maltose. Mikami et al. and Yoshigi et al. (Applicant's IDS) specifically teach a mutant β -amylase of Barley with increased thermostability. However, the claims encompass β -amylase enzyme from any source, and do not encompass mutant enzymes. Furthermore, neither the specification nor Applicant's cited reference provide guidance to one skilled in the art about the specific regions in conserved or non-conserved domains of any β -

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amylase enzyme that could be altered so that the altered β -amylase enzyme exhibits increased thermostability and reduce inhibition by maltose. Accordingly, undue experimentation would have been required by a skilled artisan to determine how to modify any β -amylase sequence to increase enzyme thermostability and reduce inhibition by maltose. Accordingly, the rejection is maintained.

8. Claims 6-7 and 25-26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in Office action mailed March 13, 2006. Applicants traverse the rejection in the paper filed August 17, 2006.

Applicants argue that amylase enzymes that are thermostable or that exhibit reduced inhibition by maltose are known in the art to an ordinarily skilled artisan (response, page 10, lines 12-15).

Applicant's arguments were fully considered but were not found persuasive. Claims 6, 7, 25 and 26 encompass structures that are not described in the specification or taught in the prior art. Examiner maintains that Applicants have failed to correlate said undisclosed structures of β -amylases to the function of increased thermostability or reduced inhibition by maltose. Thus, it clearly implies that Applicants have failed to reduce their broadly claimed genus to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written

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Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Claim Rejections - 35 USC § 103

9. Claims 1-4, 7-11, 15-21, 23, 24-30, 34-39 remain and newly added claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gausing et al. (United States Patent No. 5,498,832, issued March 12, 1996), in view of Seki et al. (The Plant Cell, 13: 61-72, 2001), for the reasons of record stated in Office action mailed on March 13, 2006. Applicants traverse the rejection in the paper filed August 17, 2006

Applicants argue that Seki et al. reference teach increased expression of numerous genes in a plant response to drought or cold stress, of which β -amylase is but one, the reference does not teach the function of amylase expression or what effects on the plant result from amylase expression. Applicants further argue that the cited references do not teach or suggest that overexpression of β -amylase in a plant can provide the plant with increased resistance to environmental stress conditions. Furthermore, Applicants argue that one finds neither the suggestion of the claimed invention nor the required expectation of success (response, page 11, lines 12-25).

Applicant's arguments were fully considered but were not found persuasive. Examiner maintains that Seki et al. clearly teach that β -amylase expression is up-regulated by at least 4.4 times in response to an environmental stress, such as cold. Furthermore, reference also teaches that β -amylase is the stress-inducible target gene for the transcription factor gene DREB1A which are well known to be up-regulated during plant's exposure to stress. Accordingly, it would have been prima facie obvious

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to one of ordinary skill in the art to have been motivated to overexpress Seki et al. β -amylase in any plant using any method of plant transformation including the one taught by Guasing et al. to obtain a stress resistant transgenic plant with reasonable expectation of success. Furthermore, it would have been obvious to breed said transgenic plant for the purpose propagation and maintaining homozygosity of the transgene in the transgenic plant population.

Accordingly, the rejection is maintained.

10. Claims 1-4, 8-13, 15-23, 25-23, 28-32, 34-39 remain and newly added claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gausing et al. (United States Patent No. 5,498,832, Issued March 12, 1996) in view of Seki et al. (The Plant Cell, 13: 61-72, 2001) and Grover et al. (Current Science, 80:206-216, January 2001) for the reasons of record stated in Office action mailed on March 13, 2006. Applicants traverse the rejection in the paper filed August 17, 2006.

Applicants addressed this rejection with the 103 rejection above. Applicant's arguments are not found persuasive for the reasons discussed above.

Accordingly, the rejection is maintained.

Summary

11. Claims 1-4, 6-13, 15-23, 25-32, 34-39 and 41 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §

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706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER